Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13202

3 - OUTPATIENT

11/11/98 [redacted] Chart # [redacted]

[redacted] been having abdominal pain for the past two and a half years. She states that it starts around the time of her period. This present episode started two weeks ago after the end of her last period. She describes it as crampy and across her lower abdomen. She denies vaginal discharge. No GI complaint.

PX: Her abdomen is benign. No CVA tenderness. No distress. Chest is clear. Stool for occult blood negative. Urine 2+ protein. Blood was drawn for CBC sed. rate LFT's, BUN and creatinine. She will be followed by her gynecologist in the clinic at [redacted] She was supposed to follow up there for a repeat pelvic ultrasound. She indeed has ovarian cysts however, has been negligent in following up. She was referred back to clinic for pelvic and further evaluation including ultrasounds.

[redacted]

Date 11/16/98 Age Wt

P BP 122/74 Meds

Nurse

11/16/98

Pt. is a 22 yr-old girl who comes to the office for f/u of abdominal pain and elevated creatinine. It appears that she has been having this pain for the last 1½ weeks. She describes it as right flank pain, with some tenderness on palpation over the posterior rib-cage, spreading around to her entire abdomen. She also notes constipation, having moved her bowels once only in the last week. She has also been very thirsty and notes polyuria. She denies any other complaints at this time. No fevers, no dysuria and no vomiting. She gets these episodes periodically. Her last one was 3 mos. ago. She is on no medications other than Triphasil birth control pills. She did use some OTC diet pill a week prior to the onset of her symptoms, but she denies any other OTC medications, particularly NSAID's or diuretics. There is family Hx of diabetes in her grandparent and gestationsl diabetes in her Mom. No family Hx of renal disease or autoimmune-type disorders. No other complaints.

PX: On exam, she appears alert and oriented. No obvious dis-tress. She is afebrile. BP is 122/74. She does have some tenderness on palpation of the posterior ribcage. Her abdomen is otherwise soft with normal bowel sounds. She is obese. She does have a diffuse tenderness throughout, possibly worse in the left lower quadrant and the right upper quadrant. There is no [redacted]

(Cont. next pg.)

11/16/98 [redacted] [redacted]

(Cont.)

rebound or guarding. No masses or organomegaly.

Urinalysis done today was WNL.

IMPRESSION: Abdominal Pain associated with Constipation, Polyuria, Polydypsia, and Elevated Creatinine, etiology unclear at this time.

PLAN: Results of her renal bladder ultrasound were reviewed. These were normal. Bloodwork done today for repeat BUN Creatinine. Will also check Glucose, ESR, ANA as well as electrolytes. This pt. has no insurance. Further treatment pending the above test results.

[redacted] [redacted] M.D. [redacted]

Date 11/20/98 Age 22 Wt.

T P BP 120/86 Meds

Nurse [redacted]

HX: Pt is 22 yr old comes to office today for f/u of renal failure, she was recently DX with Nephrogenic Diabetes Insip. with acute renal failure secondary to some herbal OTC preparations, she was discharge from the hospital 2 days ago and continue to have some polydypsia but feels that her polyuria has improved. There areno new complaints.

PX: Exam is benign, she has no further flank pain or abdominal pain, her UA today is normal, blood work done today for BUN and creatinine and will also check her ESR this was elevated in the past, further treatment and evaluationn pending above results.

[redacted]

11/23/98

BUN 30
CREAT 2.4
ESR 49

} as

1 month

[redacted]

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2/4,5/99 JAH
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[redacted]

LAB REPORTS

PATIENT NAME: [redacted] CHART NO: [redacted] TEL: _____

DATE: 11/11/98 TIME [redacted] MD/P[redacted]

ALLERGIES _____

		Tech. Init.
GLUCOSE mg/dl	_____	_____
GLYCOHEMOGLOBIN %HbAlc	_____	_____
HEMOGLOBIN g/dl	_____	_____
HEMATOCRIT %	_____	_____
THROAT CULTURE	Grp A, B-Hemolytic Strep. +/- _____	_____

URINE- LABSTIX Tech. _____

pH	5, 6, 6.5, 7, 7,5, 8, 8.5
PROTEIN	neg., trace, 30 +, 100 ++, 300 +++, 2000 ++++
GLUCOSE	neg., .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000
KETONES	neg., trace 5, small 15, mod. 40, large 80-160
BLOOD	neg., tr. or mod. nonhemol., hemol. tr.+, mod. ++, large +++

URINE - MULTISTIX Tech. [redacted]

LEUCOCYTES	neg., trace, small +, mod. ++, large +++
NITRITE	neg., pos.
UROBILINOGEN	normal 0.2, 1, 2, 4, 8
PROTEIN	neg., trace, 30 +, 100 ++, 300 +++, 2000 ++++
pH	5, 6, 6.5, 7, 7,5, 8, 8.5
BLOOD	neg., tr. small or mod. nonhemol., hemol. tr., small+, mod. ++, large +++
SPEC. GRAVITY	1.0/ D
KETONE	neg., trace 5, small 15, mod. 40, large 80-160
BILIRUBIN	neg., small +, mod. ++, large +++
GLUCOSE	neg., .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000

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STOOL FOR OCCULT BLOOD + x_____, - _____ Tech. _____

[redacted]

[redacted]

Laboratory Report

[redacted]

Patient Name	Patient ID	Accession No	Age / Date of Birth	Sex	Date Collected	Time Collected
[redacted]	[redacted]	[redacted]	[redacted]	N	11/10/98	15:

Requesting Physician / Remarks / Patient Telephone No	Fast Sp	Total Volume	Date Received	Date Reported	Report Status	Page
PT # [redacted]		N	11/12/98	11/12/98	FINAL	

Test	Results: Out of Range	Results: Within Range	Reference Range	Units
CBC W/ DIFF & PLT				
WBC		11.3	3.9-11.4	X10X9/L
RBC		4.27	3.80-5.80	X10X12/L
HGB		12.6	11.6-17.1	G/DL
HCT		37.9	34.0-50.0	%
MCV		88.6	80.0-96.0	FL
MCH		29.4	26.8-33.2	PG
MCHC		33.2	32.0-36.0	G/DL
RDW CV		13.1	11.0-15.0	%
NEUTROPHILS %		75.4	38.0-80.0	%
NEUTROPHILS ABS.	8.52		1.65-8.50	X10X9/L
LYMPHOCYTES %		17.6	15.0-49.0	%
LYMPHOCYTES ABS.		1.99	1.05-3.50	X10X9/L
MONOCYTES %		5.7	0.0-13.0	%
MONOCYTES ABS.		0.64	0.04-1.00	X10X9/L
EOSINOPHILS %		0.7	0.0-8.0	%
EOSINOPHILS ABS.		0.08	0.00-0.60	X10X9/L
BASOPHILS %		0.6	0.0-2.0	%
BASOPHILS ABS.		0.07	0.000-0.125	X10X9/L
PLATELET ESTIMATE		NL	NL	
PLATELET COUNT		*	140-400	X10X9/L
* UNABLE TO PROVIDE AN ACCURATE PLATELET COUNT DUE TO PLATELET CLUMPING.				
RBC MORPHOLOGY		NL		
ESR (WESTERGREN)		*	0-20	MM/HR
* SPECIMEN IS GREATER THAN 24 HOURS OLD, UNABLE TO PERFORM ESR.				
UREA NITROGEN	29		6-26	MG/DL
CREATININE (SERUM)	3.1		0.5-1.6	MG/DL
AST (SGOT)		15	0-40	U/L
ALT (SGPT)		10	0-55	U/L

SEX WAS NOT INDICATED ON THE REQUISITION, THEREFORE, ABNORMAL RESULTS HAVE NOT BEEN FLAGGED FOR SEX-SPECIFIC TESTS.

* END OF FINAL REPORT *

Report Received by [redacted] on 11/12/98 e-mail / o-fax

Route

Reviewed by [redacted] 11/14/98

Action

MedWatch #13202
2/4,5/99 JAH

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[redacted]

[redacted]

Name: [redacted]
Sex: F Age: 22 YRS DOB: [redacted]
MED REC:
Acc Number: [redacted]
Date: 11/13/98 Loc [redacted]

Copy To: [redacted]

Referring Dr.
Ordering MD:

ULTRASOUND

US RENAL [redacted]

HISTORY: RENAL FAILURE.

Ultrasound examination of the kidneys was performed. The left kidney measures 12.5 cm and the right kidney measures 13.6 cm. Both kidneys are isoechoic with the adjacent liver and spleen. Medical renal disease is not excluded. There is no evidence for hydronephrosis. No renal calculi are demonstrated. There is no evidence for aortic aneurysm.

IMPRESSION:
Bilaterally, there is no evidence for hydronephrosis.

Isoechoic renal parenchyma when compared to the liver. Medical renal disease is not excluded. Correlation with BUN and creatinine is recommended.

DICTATED BY: [redacted] M.D.

[redacted]

14NOV1998
15NOV1998
[redacted]

US BLADDER [redacted]

HISTORY: RENAL FAILURE.

Ultrasound examination of the bladder was performed. No bladder wall thickening is demonstrated. There is no post-void residual. Uterus and ovaries appear normal.

IMPRESSION:
Negative ultrasound examination of the bladder.

DICTATED BY: [redacted] M.D.

[redacted]

14NOV1998
15NOV1998
[redacted]

PAGE: 1 * END OF REPORT *

Report Received by [redacted] on
11/16/98 e-mail / ~~e-fax~~
Route
Reviewed by
Action

MedWatch #13202
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Page 2 document continues

[redacted]

LAB REPORTS

PATIENT NAME: [redacted] CHART NO: [redacted] TEL: _____

DATE: 11/16/98 TIME _____ MD/PA [redacted]

ALLERGIES _____

		Tech. Init.
GLUCOSE mg/dl	_____	_____
GLYCOHEMOGLOBIN %HbAlc	_____	_____
HEMOGLOBIN g/dl	_____	_____
HEMATOCRIT %	_____	_____
THROAT CULTURE	Grp A, B-Hemolytic Strep. +/- _____	_____

URINE- LABSTIX Tech. _____

pH	5, 6, 6.5, 7, 7,5, 8, 8.5
PROTEIN –	neg., trace, 30 +, 100 ++, 300 +++, 2000 ++++
GLUCOSE	neg., .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000
KETONES	neg., trace 5, small 15, mod. 40, large 80-160
BLOOD	neg., tr. or mod. nonhemol., hemol. tr.+, mod. ++, large +++

URINE - MULTISTIX Tech. [redacted]

LEUCOCYTES	neg., trace, small +, mod. ++, large +++
NITRITE	neg, pos.
UROBILINOGEN	normal 0.2, 1, 2, 4, 8
PROTEIN	neg, trace, 30 +, 100 ++, 300 +++, 2000 ++++
pH	5, 6, 6.5, 7, 7,5, 8, 8.5
BLOOD	neg, tr. small or mod. nonhemol., hemol. tr., small+, mod. ++, large +++
SPEC. GRAVITY	1.015
KETONE	neg, trace 5, small 15, mod. 40, large 80-160
BILIRUBIN	neg, small +, mod. ++, large +++
GLUCOSE	neg, .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000

STOOL FOR OCCULT BLOOD + x_____, - _____ Tech. _____

MedWatch #13202
2/4,5/99 JAH

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000007

[redacted]

[redacted]

Laboratory Report

[redacted]

Patient Name	Patient ID	Accession No	Age / Date of Birth	Sex	Date Collected	Time Collected
[redacted]	[redacted]	[redacted]	[redacted]	F	1./16/	93 00:

Requesting Physician / Remarks / Patient Telephone No	Fast Sp	Total Volume	Date Received	Date Reported	Report Status	Page
PT # [redacted]		N	1./16/	9& 1-/17/	98 FINAL	

Test	Results		Reference Range	Units
	Out of Range	Within Range		
ESR (WESTERGREN)	*75		0-20	MM/HR
GLUCOSE		82	65-109	MG/DL
* THE FASTING STATUS OF THE PATIENT WAS EITHER NON-FASTING OR WAS NOT INDICATED ON THE REQUISITION. IF THIS SPECIMEN WAS NON-FASTING, USE A REFERENCE RANGE OF 65-125 MG/DL.				
UREA NITROGEN	45		6-26	MG/DL
CREATININE (URINE)	4.9		0.5 1.3	MG/DL
SODIUM		142	135-145	MMOL/L
POTASSIUM		5.1	3.5-5.3	MMOL/L
CHLORIDE		108	96-109	MMOL/L
CO2		20	20-31	MMOL/L
ANION GAP		14	3-19	
ANTI-NUCLEAR AB W/REFLEX ANA (HEP 2)		NEGATIVE	NEGATIVE	

* END OF FINAL REPORT *

Report Received by [redacted] on
11-12-98 e-mail / o-fax
Route [redacted]
Reviewed by
Action

MedWatch #13202
2/4,5/99 JAH
Ex #1 / 11 of 16

[redacted]

[redacted]

LAB REPORTS [redacted]

PATIENT NAME: [redacted] CHART NO: [redacted] TEL: _____

DATE: 11/20/98 TIME _____ MD/PA [redacted]

ALLERGIES _____

		Tech. Init.
GLUCOSE mg/dl	_____	_____
GLYCOHEMOGLOBIN %HbAlc	_____	_____
HEMOGLOBIN g/dl	_____	_____
HEMATOCRIT %	_____	_____
THROAT CULTURE	Grp A, B-Hemolytic Strep. +/- _____	_____

URINE- LABSTIX Tech. _____

pH	5, 6, 6.5, 7, 7,5, 8, 8.5
PROTEIN	neg., trace, 30 +, 100 ++, 300 +++, 2000 ++++
GLUCOSE	neg., .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000
KETONES	neg., trace 5, small 15, mod. 40, large 80-160
BLOOD	neg., tr. or mod. nonhemol., hemol. tr.+, mod. ++, large +++

URINE - MULTISTIX Tech. [redacted]

LEUCOCYTES	neg., trace, small +, mod. ++, large +++
NITRITE	neg., pos.
UROBILINOGEN	normal 0.2, 1, 2, 4, 8
PROTEIN	neg., trace, 30 +, 100 ++, 300 +++, 2000 ++++
pH	5, 6, 6.5, 7, 7,5, 8, 8.5
BLOOD	neg., tr. small or mod. nonhemol., hemol tr, small+, mod. ++, large +++
SPEC. GRAVITY	1.0 20
KETONE	neg., trace 5, small 15, mod. 40, large 80-160
BILIRUBIN	neg., small +, mod. ++, large +++
GLUCOSE	neg., .1- trace, .25-250 mg, .5-500, 1-1000, 2-2000

STOOL FOR OCCULT BLOOD + x_____, - _____ Tech. _____

MedWatch #13202
2/4,5/99 JAH

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[redacted]

[redacted]

Laboratory Report

[redacted]

[redacted]

Patient Name	Patient ID	Accession No	Age / Date of Birth	Sex	Date Collected	Time Collected
[redacted]	[redacted]	[redacted]	[redacted]	F	11/20/98	00:0

Requesting Physician / Remarks / Patient Telephone No	Fast Sp	Total Volume	Date Received	Date Reported	Report Status	Page
PT # [redacted]	N		11/21/98	11/21/98	FINAL	1

Test	Results: Out of Range	Results: Within Range	Reference Range	Units
ESR (WESTERGREN)	49		0-20	MM/HR
UREA NITROGEN	30		6-26	MG/DL
CREATININE (SERUM)	2.4		0.5-1.3	MG/DL

* END OF FINAL REPORT *

Report Received by [redacted] on
11-23-98 ~~e~~-mail / e-fax
Route [redacted]
Reviewed by [redacted]
Action [redacted]

MedWatch #13202
2/4,5/99 JAH
Ex #19 13 of 16

000010

[redacted]

[redacted]

Date 12-15-98 Age Wt.

T P BP Meds

Nurse

[redacted]

follow up. [redacted]

Date 12-15-98 Age 22 Wt

T 98.4 P 68 BP 110/80 Meds

Nurse [redacted]

[redacted]

..X: Pt came because she has found a lump behind her left knee, it does not bother her.

PX: This pt appears to have a small Baker Cyst behind her left knee, there is no redness or tenderness, her calf appears normal. Explained to pt that shemost likely she had this for a long time and it has not bothered her, at this point I recommend not workup or treatment however explained to her the risk of rupture and also advised her that if it gets larger or painful to call me and she will be referred to ORtho.

#2- [redacted] pt is feeling fine she is not using herbs anymore blood test on this pt was done and she was instructed to call Dr [redacted] on Mon to discuss results.

[redacted]

[redacted]

MedWatch #13202
2/4,5/99 JAH

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Laboratory Report

[redacted]

[redacted]

Patient Name	Patient ID	Accession No	Age / Date of Birth	Sex	Date Collected	Time Collected
[redacted]	[redacted]	[redacted]		F	12/18/98	00:

Requesting Physician / Remarks / Patient Telephone No	Fast Sp	Total Volume	Date Received	Date Reported	Report Status	Page
[redacted]		N	12/19/98	12/19/98	FINAL	

Test	Results Out of Range	Results Within Range	Reference Range	Units
CBC W/ DIFF & PLT				
WBC		8.8	3.9-11.4	X10X9/L
RBC		4.43	3.80-5.10	X10X12/L
HGB		13.3	11.6-15.2	G/DL
HCT		39.0	34.0-45.0	%
MCV		87.9	80.0-96.0	FL
MCH		30.1	26.8-33.2	PG
MCHC		34.2	32.0-36.0	G/DL
RDW CV		13.8	11.0-15.0	%
MPV	11.8		7.5-11.5	FL
NEUTROPHILS %		64.0	38.0-80.0	%
NEUTROPHILS ABS.		5.63	1.70-8.50	X10X9/L
LYMPHOCYTES %		30.0	15.0-49.0	%
LYMPHOCYTES ABS.		2.64	1.10-3.50	X10X9/L
MONOCYTES %		4.3	0.0-13.0	%
MONOCYTES ABS.		0.38	0.04-1.00	X10X9/L
EOSINOPHILS %		1.5	0.0-8.0	%
EOSINOPHILS ABS.		0.13	0.03-0.55	X10X9/L
BASOPHILS %		0.2	0.0-2.0	%
BASOPHILS ABS.		0.02	0.000-0.125	X10X9/L
PLATELET ESTIMATE		NL	NL	
PLATELET COUNT		177	150-400	X10X9/L
RBC MORPHOLOGY		NL		
ESR (WESTERGREN)	51		0-20	MM/HR
AUTOMATED CHEMISTRIES				
GLUCOSE		89	65-109	MG/DL
* THE FASTING STATUS OF THE PATIENT WAS EITHER NON-FASTING OR WAS NOT INDICATED ON THE REQUISITION. IF THIS SPECIMEN WAS NON-FASTING, USE A REFERENCE RANGE OF 65-125 MG/DL.				
UREA NITROGEN		15	6-26	MG/DL
CREATININE (SERUM)		1.3	0.5-1.3	MG/DL
UREA NITROGEN/CREATININE		12	7-23	
SODIUM		139	135-145	MMOL/L
POTASSIUM		4.4	3.5-5.3	MMOL/L
CHLORIDE		107	96-109	MMOL/L
CO2		24	20-31	MMOL/L
ANION GAP		8	3-19	
CALCIUM		9.7	8.6-10.4	MG/DL

MedWatch #13202
2/4,5/99 JAH
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PAGE 1: CONTINUED ON PAGE 2

[redacted]

[redacted]

Laboratory Report

[redacted]

[redacted]

Patient Name	Patient ID	Accession No	Age / Date of Birth	Sex	Date Collected	Time Collected
[redacted]		[redacted]	[redacted]	F	12/18/98	00:

Requesting Physician / Remarks / Patient Telephone No	Fast Sp	Total Volume	Date Received	Date Reported	Report Status	Page
[redacted]		N	12/19/98	12/19/98	FINAL	

Test	Results: Out of Range	Results: Within Range	Reference Range	Units
PHOSPHORUS		3.2	2.2-4.6	MG/DL
ALK PHOS, TOTAL		85	30-110	U/L
AST (SGOT)		11	0-30	U/L
ALT (SGPT)		12	0-34	U/L
GGTP		35	0-55	U/L
BILIRUBIN, TOTAL		0.3	0.2-1.2	MG/DL
PROTEIN, TOTAL		7.8	6.2-8.2	G/DL
ALBUMIN		4.2	3.5-5.0	G/DL
GLOBULIN		3.6	2.1-3.8	G/DL
A/G RATIO		1.2	1.0-1.9	
LDH, TOTAL		117	85-220	U/L
URIC ACID		6.6	2.0-7.5	MG/DL
CHOLESTEROL		229	120-199	MG/DL
TRIGLYCERIDES		334	40-199	MG/DL
* THE TRIGLYCERIDES REFERENCE RANGE IS VALID FOR A 12-HOUR FASTING SPECIMEN.				
IRON		60	30-150	MCG/DL

* END OF FINAL REPORT *

Report Received by [redacted] on
12-21-98 e-mail / o-fax
Route [redacted]
Reviewed by
Action [redacted]

MedWatch #13202
2/4,5/99 . JAH

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[redacted]